In the Claims:

1-38. (Previously canceled).

39-43. (Presently canceled).

44. (Presently amended) An isolated nucleic acid comprising:

(a) ~~a nucleic acid sequence encoding the polypeptide shown in Figure 118 (SEQ ID NO: 339);~~

~~(b) a nucleic acid sequence encoding the polypeptide shown in Figure 118 (SEQ ID NO: 339), lacking its associated signal peptide;~~

~~(c)~~ the nucleic acid sequence shown in Figure 117 (SEQ ID NO:338);

~~(d)~~ (b) the full-length coding sequence of the nucleic acid sequence shown in Figure 117 (SEQ ID NO:338); or

~~(e)~~(c) the full-length coding sequence of the cDNA deposited under ATCC accession number 209490,

wherein said isolated nucleic acid is amplified in ~~encodes a polypeptide associated with the formation or growth of~~ lung or colon tumor.

45-46. (Presently canceled).

47-48. (Previously canceled).

49. (Previously added) The isolated nucleic acid of Claim 44 comprising the nucleic acid sequence shown in Figure 117 (SEQ ID NO:338).

50. (Previously added) The isolated nucleic acid of Claim 44 comprising the full-length coding sequence of the nucleic acid sequence shown in Figure 117 (SEQ ID NO:338).

51. (Previously added) The isolated nucleic acid of Claim 44 comprising the full-length coding sequence of the cDNA deposited under ATCC accession number 209490.

52-54. (Presently canceled)

55. (Presently amended) A vector comprising the nucleic acid of Claim 44 ~~39~~.

56. (Previously added) The vector of Claim 55, wherein said nucleic acid is operably linked to control sequences recognized by a host cell transformed with the vector.

57. (Previously added) A host cell comprising the vector of Claim 55.

58. (Previously added) The host cell of Claim 57, wherein said cell is a CHO cell, an *E. coli* or a yeast cell.

Remarks/Arguments

Claims 39-46 and 49-58 are pending in this application. Claims 39-43, 45-46 and 52-54 are presently canceled. Claims 47 and 48 were previously canceled. Although the Examiner has withdrawn some prior rejections, Claims 52-54 remain rejected under 35 USC § 112, second paragraph; all claims remain rejected under 35 USC §101/112, first paragraph for alleged lack of utility and Claims 39-44, 49 and 52-58 remain rejected under 35 USC §102(b) /103(a) over GeneBank Accession No. AB037823, Stratagene Cloning Systems Catalog.

Applicants respectfully traverse these rejections to the pending claims.

35 U.S.C.§112, Second paragraph Rejections

Claims 52-54 remain rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

In view of the cancellation of claims 52-54, this rejections is moot.

35 U.S.C. §101 Utility /35 U.S.C. §112, First paragraph Rejections

Claims 39-46 and 49-58 remain rejected under 35 U.S.C. §101 because, according to the Examiner, the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. In addition, claims 39-46 and 49-58 also remain rejected under 35 U.S.C. §112, first paragraph because the claimed invention is not allegedly supported by either a specific and substantial asserted utility or a well established utility, and one skilled in the art would not know how to use the claimed invention.

The Examiner acknowledges that the TaqMan™ PCR assay can accurately and reproducibly assess gene amplification, but asserts that it is necessary to account for the possibility of aneuploidy. The Examiner also asserts that "the encoded polypeptide" would not have utility since "it does not necessar(il)y (sic) follow that an increase in gene copy number results in increased gene expression and increased protein expression, such that the polypeptide would be useful diagnostically or as a target for cancer drug development."

In view of the cancellation of Claims 39-43, 45-46 and 52-54, the rejections to these claims are rendered moot. Applicants respectfully traverse these rejections to the remaining claims.

Initially, regarding the Examiner's point on aneuploidy, Applicants submit that the mechanism of gene amplification, whether by aneuploidy or gene duplication or any other mechanism, is irrelevant to the utility of the gene as a diagnostic marker for detecting cancer. In aneuploidy where chromosome loss or gain occurs, a change in DNA copy number can still be detected by the TaqMan™ PCR assay. In addition, enclosed is a Declaration by Avi Ashkenazi, Ph.D., an expert in the field of cancer biology and an inventor of the present application. As Dr. Ashkenazi explains,

> even when amplification of a cancer marker gene does not result in significant over-expression of the corresponding gene product, this very absence of gene product over-expression still provides significant information for cancer diagnosis and treatment. Thus, if over-expression of the gene product does not parallel gene amplification in certain tumor types but does so in others, then parallel monitoring of gene amplification and gene product over-expression enables more accurate tumor classification and hence better determination of suitable therapy. In addition, absence of over-expression is crucial information for the practicing clinician. If a gene is amplified but the corresponding gene product is not over-expressed, the clinician accordingly will decide not to treat a patient with agents that target that gene product.

Thus, Applicants have asserted a utility for the DNA in the diagnosis of lung and colon cancer, based upon the disclosure in the specification, especially in Example 92, and Applicants submit that one of skill in the art would know how to use the claimed nucleic acids of the invention to diagnose cancer.

Regarding the Examiner's point about utility for "the encoded polypeptide," since the claims are directed to nucleic acid molecules which are amplified in lung or colon cancer, the

Examiner's comments concerning the utility of the encoded polypeptide has no bearing on the patentability of the claimed invention.

Accordingly, the present rejections should be withdrawn.

Claim Rejections - 35 USC § 102 and § 103

Claims 39-44, 47, 49 and 52-58 were rejected under 35 USC 102(b) as "being anticipated by GenBank Accession No. AB037823 (March 14, 2000) as evidenced by the Strategene Cloning Systems catalog ."

Again, in view of the cancellation of Claims 39-43, 45-46 and 52-54, the rejection of these claims are moot. Applicants respectfully traverse these rejections to the remaining claims.

According to the Office Action, the effective date of the primary reference (GenBank Accession No. AB037823) is March 14, 2000. The date of submission of the sequence to GenBank was 31 Jan, 2000. The gene amplification data, which supports the utility of the claimed nucleic acids in the present application were first disclosed in PCT/US00/03565 filed on February 11, 2000, which is the effective priority date for this application. Therefore, relying on its submission date, AB037823 is not 102(b) art but 102(a) art.

Anticipation under 35 U.S.C. § 102 requires that "every element of the claimed invention be identically shown in a single reference." (*In re Bond*, 910 F.2d 831,832 (Fed. Cir. 1990).

According to our alignment results, AB037823 has 99% homology to the nucleic acid in SEQ ID NO: 338 and hence, is not identical to the invention claimed in claim 44 or its dependent claims. Hence, AB037823 does not anticipate the present claims.

Accordingly, the present rejection should be withdrawn.

In addition, Claim 46 was rejected under 35 USC § 103(a) as allegedly obvious over GenBank Accession No. AB037823 and in view of "Applicants' Admission on p.34, lines 5-6 and Fleming *et al.* (Dev., 124:2873-81 (1997))."

As discussed above, the primary reference AB037823 is not prior art under 102(a). Hence, the 103 rejection falls and Claim 46 is not obvious over GenBank Accession No. AB037823 and in view of "Applicants' Admission on p.34, lines 5-6 and Fleming *et al.*

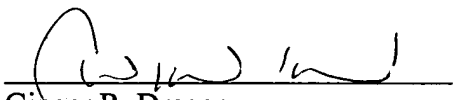
Accordingly, the present rejection should be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C81). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: October 2, 2003



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